



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,075	12/09/2005	Gang Zheng	1694.0580004/JMC/CMB	9659
26111 7590 05/07/2009 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 05/07/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,075	<b>Applicant(s)</b> ZHENG ET AL.	
	<b>Examiner</b> LAYLA BLAND	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted February 5, 2009, wherein claim 1 is amended.

Claims 1, 2, and 25 are pending and are examined on the merits herein.

#### ***Priority***

The provisional applications 60/476,648, 60/537,282, 60/540,700, and 60/548,240, upon which priority is claimed, fail to provide adequate support under 35 U.S.C. 112 for claims 1, 2, and 25 because of this application because none of the priority applications provides support for the structure BChIPP presented in claim 1. The '282 application supports the recited structure NIR664. The '240 application supports the recited structure BChIE6 presented in claim 1. However, none of the priority applications contains the recited structure BChIPP as shown in claim 1. Applicant argues that the '240 application describes 2-deoxyglucose conjugates attached to BChIPP. The '240 application describes a conjugate BChIPP-2DG, but that structure does not contain an aminothiocarbonyl group as required in instant claim 1. Claims 2 and 25 depend from claim 1 and thus also recite the BChIPP which is not supported by the priority applications.

Thus, the filing date of claims 1, 2, and 25 is deemed to be the instant filing date, June 9, 2004. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

The following rejection is maintained:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

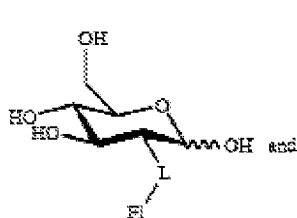
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tidmarsh et al. (US 6,989,140 B2, January 24, 2006, of record) in view of Fukuzumi et al. (J. Phys. Chem. A 2002, 106, 5105-5113, of record).

Tidmarsh et al. teach methods for cancer and pre-cancer detection by increased uptake of deoxyglucose conjugates in cancerous and pre-cancerous cells [see abstract]. Cancerous and pre-cancerous cells exhibit an enhanced rate of uptake of glucose fluorophore conjugates [column 4, lines 38-41]. The conjugates can be derived by chemically modifying 2-deoxyglucose, which is taken into and accumulated in cancerous cells and pre-cancerous cells compared to normal cells [column 4, lines 42-49]. After allowing the fluorophore glucose conjugate to accumulate in the cancerous cells, an examination can be made with a camera or other device to view or capture the fluorescence [column 4, lines 49-54]. Preferably, the fluorophore fluoresces upon excitation of light in the range of about 500 nm to 900 nm [column 6, lines 24-31].

Art Unit: 1623

Preferred fluorophores include macrocyclic fluorescent dye compounds [column 8, lines 1-5]. The fluorophores can be attached to the deoxyglucose using, for example, a fluorophore isothiocyanate [column 9, lines 64-67] or a bifunctional linker group derived from  $\text{-NH}_2$ ,  $\text{NHNH}_2$ ,  $\text{-ONH}_2$ ,  $\text{-NHC(=O)NHNH}_2$ ,  $\text{-OH}$ ,  $\text{-CO}_2\text{H}$ , or  $\text{-SH}$  [column 10, lines 26-45]. The fluorophore deoxyglucose conjugate can have the formula shown below, where L is a linker group and FI is a fluorophore [column 15, 1a]:

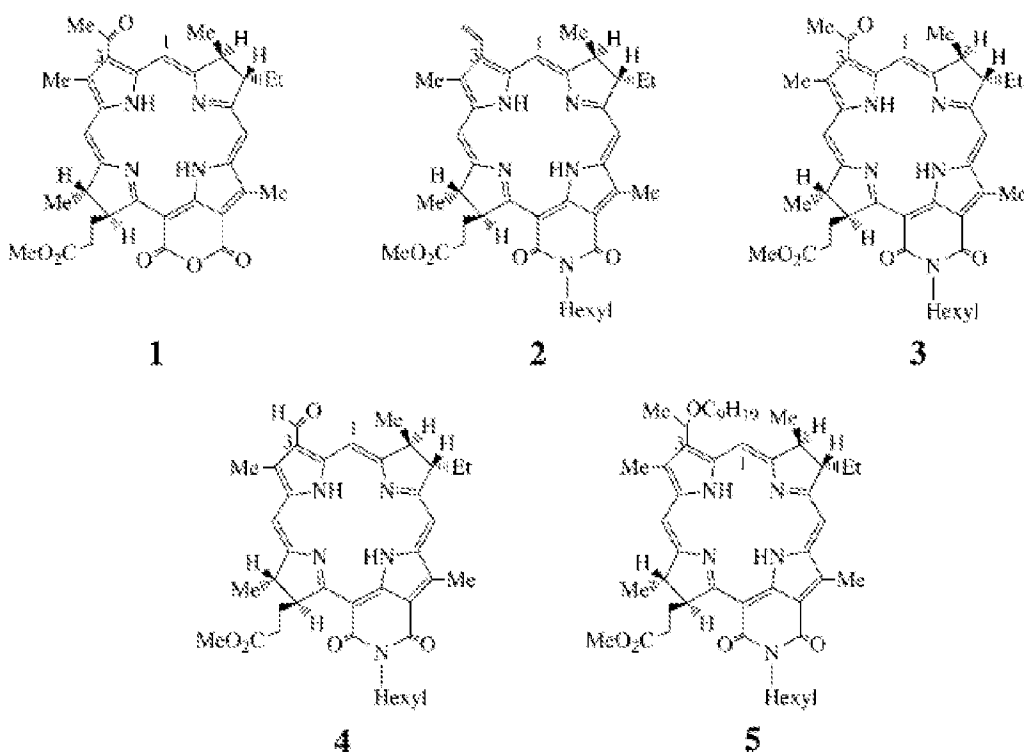


The conjugates can be administered in forms suitable for oral administration or parenteral administration and can include pharmaceutical carriers [column 17, lines 13-49].

Tidmarsh et al. do not exemplify a glucose conjugate with the elected species BChIPP as recited in claim 1.

Fukuzumi et al. teach that the following stable bacteriochlorin compounds [page 5108, Chart 1] are highly promising for potential use in photodynamic therapy due to long-wavelength absorption [see abstract]. Conversion of the five-membered isocyclic ring present in chlorophyll *a* can be converted into a fused six-member isoimide or imide ring, extending the long-wavelength absorptions [page 5105, last paragraph]. Compounds containing the six-member imide ring were more stable in vivo than those bearing a fused anhydride or isoimide ring system [page 5106, first paragraph].

Art Unit: 1623



It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare glucose conjugates with bacteriochlorins such as compound 3 taught by Fukuzumi et al. Tidmarsh et al. teach that glucose conjugates with fluorophores, including conjugates linked by isothiocyanate as shown in instant claim 1, are useful for cancer detection and Fukuzumi et al. teach that compound 3 has ideal properties for photodynamic therapy, including fluorescence within the desired wavelength range taught by Tidmarsh et al. Compound 3 is very similar to BChIPP shown in claim 1, except for the group attached to the imide. Tidmarsh et al. teach the use of an isothiocyanate linker, such as the one shown in claim 1, for attachment to a 2-deoxyglucose molecule. Thus the skilled artisan could easily conceive of preparing a

Art Unit: 1623

glucose conjugate of compounds taught by Fukuzumi et al. and could predict that the resulting conjugate would be effective for cancer detection and photodynamic therapy.

### ***Response to Arguments***

Applicant argues that Fukuzumi's compounds are different from the claimed compounds because the claimed compounds include an alkylaminothiocarbonyl group wherein Fukuzumi's compounds have a hexyl group. Applicant's argument has been considered but is not persuasive. Fukuzumi teaches the benefit of compounds containing the six-member imide ring [page 5106, first paragraph], which is also present in the claimed compound. Tidmarsh teaches the use of an isothiocyanate linker for attachment of the fluorophore to the 2-deoxyglucose molecule, to form a thiourea linkage between the two compounds [column 20, lines 48-56]. Tidmarsh also teaches that the length of the linker arm can be varied [column 14, line 40]. Thus, the skilled artisan could arrive at a conjugate having a thiourea group linking the fluorophore and the 2-deoxy glucose molecule, such as would be the case when D is BChIPP and L is NH, by following the suggestion of the prior art. The rationale to modify Fukuzumi's compound to include an alkylaminothiocarbonyl group is thus provided by the suggestions of Tidmarsh.

Applicant argues that the skilled artisan would not have a reasonable expectation of success in obtaining compounds with the same properties of that of compounds 2-5. This argument is not persuasive because the skilled artisan would have an expectation of obtaining compounds having the properties taught by Tidmarsh. Tidmarsh teaches

Art Unit: 1623

that preferred fluorophores include macrocyclic fluorescent dye compounds, which fluoresce upon excitation of light in the range of about 500 nm to 900 nm, as set forth above. Fukuzumi's compound 3 shows fluorescence at 740 and 835 nm, well within Tidmarsh's range. Tidmarsh also teaches the use of an isothiocyanate moiety to create a thiourea linkage between the fluorophore and the 2-deoxyglucose compound. Thus, the skilled artisan would expect that a conjugate prepared from Fukuzumi's compounds and having the thiourea linkage would be effective.

For these reasons, the rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/  
Examiner, Art Unit 1623